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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,768	02/04/2004	David A. Horwitz	A-68983-2 (469443-65)	2359
	7590		RMS	
Richard F. Trecartin DORSEY & WHITNEY LLP Suite 3400 Four Embarcadero Center San Francisco, CA 94111-4187			EXAMINER JALLA, SANJOO	
			ART UNIT	PAPER NUMBER
			1644	
DATE MAILED: 02/28/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,768	HORWITZ, DAVID A.	
	Examiner	Art Unit	
	Sanjoo Shree Jalla	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-6 are pending.
2. Applicant's election with traverse of Group I (Claims 1-5) in a reply filed 01/03/ 2006 is acknowledged. The traversal is on the grounds that the present application is a continuation of Patent Application No. 09/833,526, which issued on July 6, 2004 as U.S. Patent No. 6,759,035 and that the U.S. Patent and Trademark Office has taken inconsistent positions by allowing the claims of the '035 patent to issue with dependent claims of CD4+ T cells and CD8+ T cells and to then require restriction as between CD4+ T cells and CD8+ T cells in the present application. That patent issued with five claims. Claim 1 of '035 patent is to a method for decreasing graft rejection of a solid organ by a recipient. The method comprises five steps (a) through (e). Dependent Claims 3 and 4 call for PBMC from the recipient that are CD4+ T cells or naïve CD4+ T cells. Claim 5 calls for the PBMC from the recipient to be enriched for CD8+ T cells. The pending claims are directed to one or more suppressor T cells that are made according to at least the first three steps of Claim 1 of the '035 patent. As with the '035 patent, pending Claims 4, 5 and 6 call for PBMCs to be enriched for CD4+ cells, naïve CD4+ cells and CD8+ cells, respectively.

Upon reconsideration, group I has been rejoined with group II. Therefore, claims 1-6 are under examination.

3. The abstract of the disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP § 608.01(b).
4. The title of the invention is not descriptive. Applicant should restrict the title to the claimed invention. A new title is required that is clearly indicative of the invention to which the claims are directed.
5. Applicant's IDS, filed 01/31/05 is acknowledged. Reference Nos. C7, C16, C24, C35, C44, C76, C78 AND C126 in the IDS have been crossed out as they are not considered for the following reasons:
 - a) In reference No. C7, source of the reference is incorrect.
 - b) In reference No. C16, title of the reference is missing and only abstract is submitted without any source information.
 - c) In reference Nos. C24, C35 and C126, only abstract is submitted without any source information.
 - d) In reference No. C44, author is misidentified.
 - e) References C76 and C78 could not be located.
6. The U.S. Patent No. 6,759,035 cited on PTO-892 was issued from the parent Application No. 09/833,526.

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7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for **omitting essential steps**, such omission amounting to a gap between the steps. See MPEP § 2172.01.

The omitted step is the last step of isolating suppressor T cells. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. Claims 1 and 2 recite isolating peripheral blood mononuclear cells (PBMC) from a recipient and an organ donor followed by irradiating T cell-depleted mononuclear cells from said organ donor PBMC; and combining ex vivo said recipient PBMC with said donor irradiated T cell-depleted mononuclear cells and a regulatory composition comprising TGF-beta to induce one or more recipient suppressor T cells. It is unclear, after recipient suppressor T cells are induced by TGF-beta, how these suppressor T cells are isolated. What markers are used to isolate the suppressor T cells. The claims lack clear positive process steps to carry out the claimed methods.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 and 6 are rejected under 35 U.S.C. 102 (e) as being anticipated by U.S. Patent No: 6,685,936 (Oct 1999; PTO 892).

The '936 Patent teaches suppressor T cells capable of treating (i.e. decreasing) transplant rejection (see in particular column 3, lines 14-15). Further, '936 Patent teaches suppressor T cells to be CD8+ T cells (see in particular column 8, lines 23-24). However, the '936 Patent does not teach the same process of making the claimed suppressor T cells. As regards to applicant's reliance upon product-by-process limitations within the claimed methods; it is noted that the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) See MPEP 2113. The claimed compound is the same compound as taught by the '936 patent irrespective of how it is made.

The reference teachings anticipate the claimed invention.

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9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.


Claims 1-5 are rejected under 35 U.S.C. 102 (b) as being anticipated by Hall et.al. (J. Exp. Med. 1990; 171: 141-157; PTO 892).

Hall et.al. teach CD4+ suppressor T cells capable of inhibiting restoration of transplant rejection (i.e. decreasing transplant rejection) (see in particular page 154, Summary, lines 7-8). Additionally, Hall et.al. teach CD4+ suppressor T cells to be CD45R (see in particular page 152, 2nd paragraph, line 1) and that CD45R⁺ cells to be naïve cells (i.e. naïve CD4 T cells) (see in particular page 152, 2nd paragraph, lines 14-15). However, Hall et.al. do not teach the same process of making the claimed suppressor T cells. As regards to applicant's reliance upon product-by-process limitations within the claimed methods; it is noted that the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) See MPEP 2113. The claimed compound is the same compound as taught by Hall et.al., irrespective of how it is made.

The reference teachings anticipate the claimed invention.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sanjoo Jalla whose telephone number is (571) 272-4453. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.
11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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02/18/06


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